

Attorney Docket No.: DEX-0150  
Inventors: Sun et al.  
Serial No.: 09/762,021  
Filing Date: August 6, 2001  
Page 3

#### REMARKS

Claims 1-11 are pending in the instant application. Claim 2-11 have been withdrawn from consideration by the Examiner and subsequently canceled without prejudice by Applicants in this amendment. Claim 1 has been rejected. Claim 1 has been amended. Support for the amendment to claim 1 is provided in the specification at page 3, lines 3-13. No new matter is added. Reconsideration is respectfully requested in light of these amendments and the following remarks.

#### I. Finality of Restriction Requirement

The Restriction Requirement mailed November 13, 2002 has been made final. Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have canceled without prejudice non-elected claims 2-11. However, in light of the finality of this Restriction Requirement, Applicants reserve the right to file a divisional application to the canceled subject matter.

#### II. Objection to Claim 1

Claim 1 has been objected to because it recites non-elected

Attorney Docket No.: DEX-0150  
Inventors: Sun et al.  
Serial No.: 09/762,021  
Filing Date: August 6, 2001  
Page 4

limitations. Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended claim 1 to the elected subject matter.

Withdrawal of this objection is therefore respectfully requested.

### **III. Rejection of Claim 1 under 35 U.S.C. § 112, first paragraph**

Claim 1 has been rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants respectfully traverse this rejection.

MPEP § 2164 is quite clear; the invention which must be enabled by the specification is the invention being claimed. The invention being claimed in the instant application is a method for diagnosing colon cancer based upon detection of a CSG, which as taught in the specification at page 3 may comprise a polynucleotide or a polypeptide encoded thereby. Further, in accordance with the Examiner's suggestion, Applicants have amended the claim to be drawn to detecting a CSG comprising SEQ

Attorney Docket No.: DEX-0150  
Inventors: Sun et al.  
Serial No.: 09/762,021  
Filing Date: August 6, 2001  
Page 5

ID NO:1, a polynucleotide sequence.

Accordingly, the Examiner's characterization of the instant claimed invention as an *in vivo* imaging diagnostic kit based upon detection of CSG protein is incorrect.

Further, the Examiner's comments relating to the unpredictability of protein expression based upon mRNA expression and the Examiner's citation of Genbank Sequences for herpes virus 1 or herpes virus 3, suggested by the Examiner to share epitopes with the protein encoded by SEQ ID NO:1, are irrelevant since the instant claimed invention is based upon detection of a polynucleotide sequence.

Also irrelevant to the instant claimed method for diagnosing **colon** cancer, are the Examiner's comments with respect to data in Tables 1-3. The Examiner suggests that in 63 out of 81 cases, mRNA in matched normal control was higher than in cancer tissues. However, the data presented in Tables 1-3 is representative of a variety of tissues, not simply colon tissue. Thus, the Examiner's calculation of a 77% false negative rate and the suggestion that the skilled artisan would not believe the assay to function reliably is based upon improper analysis of the data.

Data in these tables relevant to the instant invention, a

Attorney Docket No.: DEX-0150  
Inventors: Sun et al.  
Serial No.: 09/762,021  
Filing Date: August 6, 2001  
Page 6

method for diagnosing colon cancer, show that 63% of colon cancer tissues compared to normal adjacent tissue showed overexpression of Cln117 (SEQ ID NO:1). Accordingly, 17 out of the total 27 colon matching samples exhibited overexpression of this colon specific marker. Thus, SEQ ID NO:1 is at least as sensitive as many useful cancer therapeutics and diagnostics that have been approved by the FDA and are commercially available. For example, Genentech's product Herceptin® and its diagnostic counterpart, the HercepTest® are very successfully commercially. Yet many publications show the relevant gene, HER-2, is overexpressed in only 30% of breast cancer patients.

Thus, contrary to the Examiner's suggestion, the specification provides sufficient guidance as well as a working example of a diagnostic method for colon cancer based upon detection of SEQ ID NO:1 which is commensurate in scope with the claimed invention. Accordingly, the specification meets the requirements of 35 U.S.C. § 112, first paragraph as set forth in MPEP § 2164.

Withdrawal of this rejection under 35 U.S.C. § 112, first paragraph, is therefore respectfully requested.

Attorney Docket No.: DEX-0150  
Inventors: Sun et al.  
Serial No.: 09/762,021  
Filing Date: August 6, 2001  
Page 7

#### **IV. Rejection of Claim 1 under 35 U.S.C. § 102(a) and 102(e)**

Claim 1 has been rejected under 35 U.S.C. § 102(a) and 102(e) as being anticipated by U.S. Patent 5,733,748. The Examiner suggests that this patent teaches a method of utilizing Human Colon Specific Gene polypeptide as a diagnostic marker for colon cancer.

Applicants respectfully traverse this rejection.

In accordance with MPEP § 2131, to anticipate a claim the reference must teach all elements of the claimed invention.

As discussed in Sections II and III, *supra*, claim 1 has been amended to specify that the CSG detected comprises SEQ ID NO:1. U.S. Patent 5,733,748 does not teach a CSG comprising SEQ ID NO:1. Accordingly, this reference cannot anticipate the claims as amended.

Withdrawal of this rejection under 35 U.S.C. § 102(a) or 102(e) is therefore respectfully requested.

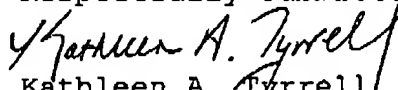
#### **V. Conclusion**

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly,

Attorney Docket No.: DEX-0150  
Inventors: Sun et al.  
Serial No.: 09/762,021  
Filing Date: August 6, 2001  
Page 8

favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



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Date: June 10, 2003

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